

3. **Keyword Search**: Keyword Search means a search of the text of ESI for one or more words or set of characters or numbers that are specified by a user.

4. **Production Load File**: Production Load File means a file accompanying any production that facilitates the use of the produced files by a document management or litigation support system. As specified further below, the Production Load File shall indicate how individual pages belong together as documents, including the parent/child (Email/Attachment) relationships of documents, and shall provide the agreed-upon metadata fields outlined below.

5. **Native Format**: Native Format means the format of ESI in which it was generated or as it is used by the Producing Party in the usual course of its business and in its regularly conducted activities.

6. **OCR**: OCR means an optical character recognition file which is created by software used in conjunction with a scanner that is capable of reading text-based documents and making such documents searchable using appropriate software.

7. **On-Line Repository**: On-Line Repository means a secure database of documents that makes documents accessible, searchable, and reviewable via the Internet.

8. **Paper Discovery**: Paper Discovery means responsive documents and things pursuant to Federal Rule of Civil Procedure 26(b)(1) and 34 which were originally created in paper format and which may or may not have been converted into digital format.

9. **Party or Parties**: Party or Parties means the named Plaintiff and/or Defendants in This Litigation, namely, Regeneron Pharmaceuticals, Inc., Novartis Pharma AG, Novartis Technology LLC, Novartis Pharmaceuticals Corporation, and Vetter Pharma International GmbH.

10. **Producing Party**: Producing Party means a Party (or non-party that avails itself of this Order) that produces ESI in This Litigation.

11. **Production Media**: Production Media means documents on readily accessible computer or electronic media as the Parties may hereafter agree upon, including CD-ROM, DVD, or external hard drive (with standard PC compatible interface).

12. **Receiving Party**: Receiving Party means a Party to whom ESI is produced.

13. **Responsive ESI**: Responsive ESI means ESI that is responsive to a Receiving Party's discovery and relevant under Federal Rule of Civil Procedure 26(b)(1) and the applicable Federal Rules of Evidence and is deemed reasonably accessible under Federal Rule of Civil Procedure 26(b)(2)(8).

14. **Sampling**: Sampling means the process of testing a designated data set for existence or frequency of Responsive ESI.

15. **This Litigation**: This Litigation means the case captioned *Regeneron Pharmaceuticals, Inc. v. Novartis Pharma AG, et al.*, No. 1:20-05502-AJN, which is currently pending in the Southern District of New York.

16. **TIFF**: TIFF (Tagged Image File Format) refers to the Group IV, 300 DPI black-and-white graphic file format for storing bit-mapped images, with multiple compression formats and resolutions.

B. SCOPE

1. **General**: The procedures and protocols set forth in this Order shall govern the production of ESI in This Litigation, unless the Parties agree in writing to change them or they are changed by the Court at the request of a Party. To the extent that non-parties produce documents in this case, the Parties agree to request that such non-parties adopt this Order.

2. **Scope of Production**: This Order provides a general framework for the production of ESI. This Order does not establish any agreement as to either the temporal or subject matter scope of discovery. The Parties shall meet and confer regarding custodial and non-custodial

sources of potentially discoverable documents, including the production of databases or other structured data.

3. **Deleted Files:** The Parties shall not be obligated under this Order to produce deleted ESI, lost as a result of the routine, good-faith operation of an electronic information system, unless the Party requesting the deleted ESI establishes that there is good cause to believe that the Producing Party intentionally deleted ESI to avoid production of ESI in This Litigation.

4. **Subsequent Orders:** This Order shall not preclude subsequent agreements between the Parties relating to ESI, nor shall it preclude any Party from seeking relief from or an amendment to this Order upon a showing of good cause.

C. **COST CONTAINMENT**

1. **Objective:** The procedures in this Order pertaining to production of ESI are subject to the development of reasonable and appropriate strategies to minimize the cost and burden that may be associated with production of ESI.

2. **Keyword Searches:** For the production of Custodial ESI, the Parties agree to conduct Keyword Searches using search terms that have been reasonably calculated in good faith to retrieve Responsive ESI. The Parties further agree that their respective search terms shall include any relevant internal project codes, to the extent such codes exist. The Parties agree to exchange their respective lists of search terms for Custodial ESI and meet and confer in good faith as necessary to resolve any disputes that may arise regarding the use of search terms or any other deficiencies in a Party's electronic document production.

3. **Devices:** The Parties agree that it is not necessary to search for information contained on cellular phones, smartphones (e.g., iPhones), tablets (e.g., iPads), or other similar portable devices, and sources not reasonably accessible due to undue burden or cost, such as company-issued computers (not in the Producing Party's possession, custody, or control) of former

employees, and personal computers; cellular phones, smartphones (e.g., iPhones), tablets (e.g., iPads), or other similar portable devices of current and former employees; external hard drives of current and former employees; and voicemail systems, legacy computer systems, backup tapes, backup systems, and disaster recovery systems. Each Party reserves the right to request that an opposing party search such devices or systems provided that the requesting party is able to show (1) a particularized and reasonable need for the information contained on such devices or systems; and (2) the unavailability of said information from alternative sources more easily accessible; and (3) the information sought will not impose an undue burden and/or cost on the Producing Party. The Parties agree to meet and confer in good faith should a dispute arise under this Paragraph, and if the Parties cannot reach an agreement, the Parties may submit the issue as a discovery dispute in accordance with the rules of the Court.

4. **Technology Assisted Review:** The Parties agree to the use of Predictive Coding, Technology Assisted Review, or computer-assisted learning for each Party's electronic document productions.

5. **Email Threading:** Where multiple email messages are part of a single "thread," a Party is only required to produce the most inclusive message for which no claim of privilege is made, and need not produce earlier, less inclusive email messages that are fully contained, including attachments, within the most inclusive email message for which no claim of privilege is made. For the avoidance of doubt, only email messages for which the parent document and all attachments are contained in the more inclusive email message will be considered less inclusive email messages that need not be produced; if the later message contains different text (such as where the later message adds in-line comments to the body of the earlier message), or does not include an attachment that was part of the earlier message, the earlier message must be produced.

Additionally, the producing party may list on any required privilege log only the most inclusive email thread.

6. **Document Families**: If one document in a document family is responsive and one or more other documents in the same document family are not responsive, only the documents that are responsive, or are parent emails to responsive attachments, will be produced. Slipsheets should be inserted as placeholders where family member documents are not produced.

7. **Cost Shifting**: Generally, the costs of production of ESI produced pursuant to this Order shall be borne by each Producing Party. However, the Court will apportion the costs of electronic discovery upon a showing of good cause by the party seeking apportionment.

D. PRODUCTION

1. **Production Format**: Unless otherwise specified herein, a Producing Party shall produce electronic documents in black-and-white, single page, 300 DPI, Group IV* tagged image file format (“TIFF”) images with corresponding extracted full text. All productions will include these additional specifications:

- a. A load file for images;
- b. A delimited load file (.dat), or any equivalent format thereof that the Parties find mutually agreeable, containing a field with the full path and filename to Native Files produced and the metadata fields identified in this paragraph D(1) (for ESI) (unless the filename is redacted);
- c. Document level .txt files, or any equivalent format thereof that the Parties find mutually agreeable, for all native documents containing extracted full text; provided, however, that OCR text can be provided if extracted text is not available (in which case the Parties shall meet and confer regarding the reason extracted text is not available) or if the document has been redacted

pursuant to this protocol or the Protective Order that the Court will enter in This Litigation;

- d. Bates number branding and appropriate Confidentiality designations (if any) on the face of the image; and
- e. Slipsheets may be used as placeholders for any family member documents or email attachments that are not responsive, which should indicate “non-responsive attachment not produced” or language to that effect.

2. **Production of Native Format ESI:**

- a. A Producing Party shall produce Excel spreadsheets, audio files, and video files in their Native Format. For Excel spreadsheets with redactions, the Production Party shall either: (1) produce them as TIFF images, but shall ensure that the images are legible, and the Parties shall meet and confer with regard to any issues with how spreadsheets with redactions are compiled (*e.g.*, cell numbers and headers); or (2) produce them as Native Excel files.
- b. If production in Native Format is necessary to decipher the meaning, context, or content of a document produced in TIFF, the Producing Party will honor reasonable requests for either the production of the original document for inspection and copying or production of the document in Native Format.
- c. To the extent it exists and is available, the following metadata contained in or associated with each Native File will be produced: original file name, source, date created, last modified date, custodian/witness name, author, sender, and recipient. The Native Format document shall be renamed with

a Bates number. For each document whose Native Format is a multimedia (video) file, a TIFF placeholder shall be produced in addition to the Native File.

3. **Production Load File:** To the extent production is made in an electronic format susceptible to creation of a Production Load File (and, where an electronic format is not susceptible to the creation of a Production Load File, the Parties shall meet and confer regarding the reason a Production Load File is not available), the Producing Party shall provide a Production Load File to accompany the TIFF images that are produced to facilitate the use of the produced images by a document management or litigation support system.

- a. Production Load Files shall indicate document breaks, page breaks within a single document (but if, and only if, the Producing Party creates or uses page breaks when it processes its documents), and contain the parent/child (Email/Attachment) relationships of documents, when possible.
- b. For all documents produced, regardless of whether produced in TIFF image or native format, the following metadata fields will be provided in the Production Load File for each document to the extent that such information is available at the time of collection and processing: beginning bates, end bates, beginning attachment, end attachment, parent bates, child bates, original file name, email subject, source, date created, last modified date, date received, date sent, file extension, custodian/witness name, author, sender, and recipient (e.g., broken out by “to,” “cc,” and “bcc” in emails).
- c. If a Producing Party intends to de-duplicate within non-custodial files, or between custodial files and non-custodial files, the metadata provided in the

Production Load File shall indicate from which other source(s) the documents were de-duplicated.

- d. To the extent that a document is produced in redacted form, any redactions shall be clearly indicated on the face of the document, and the Production Load File accompanying that document's production should indicate, for each redacted document, that there is a redaction. Where a responsive document contains both redacted and non-redacted content, the Producing Party shall produce the remainder of the non-redacted portions of the document. The production of a document in a redacted form does not affect the Producing Party's obligation to properly document and substantiate the assertion of privilege over the content on a privilege log. Except as provided above in paragraph D(2)(a), documents that are to be produced in Native Format, but that require redactions, may be produced as TIFF images (with extracted text) with the relevant portions redacted, or if a TIFF image production is not technically feasible, the Producing Party may produce a copy of the Native File with the relevant portions replaced with "[REDACTED]" or a similar mark. If modification of a Native File is required for redaction purposes, metadata information associated with that file should remain unchanged unless it also requires redaction.

4. **Color:** Documents containing color need not be originally produced in color. If an original document contains color necessary to understand the meaning or content of the document, however, the Producing Party shall honor reasonable requests for either the production of an original document for inspection and copying, or production of a color image of the document.

5. **De-duplication of Production:** A Producing Party is only required to produce a single copy of a responsive document. A Producing Party may de-duplicate exact duplicates based on the files' MD5-Hash value or SHA-1 hash values prior to production in a manner that does not break up document families (such as emails and attachments), but the original ESI shall be preserved. A Producing Party is further permitted to de-duplicate stand-alone documents or entire documents using near-duplicate identification technology, provided, however, that only documents identified by such technology at 100% near duplicates will be de-duplicated. For purposes of this paragraph, 100% near duplicates are documents that have identical text content, embedded files, and attachments. When comparing document families, if a parent document is an exact duplicate or 100% near duplicate but one or more attachments or embedded files are not exact duplicates or 100% near duplicates, neither the attachments or embedded files, nor the parent document, will be de-duplicated. A Producing Party is permitted to de-duplicate stand-alone documents or entire document families vertically within each custodian or horizontally (also referred to as globally) across custodians. A metadata field listing all custodians who have possessed a document shall be included in the list of metadata fields for produced documents.

6. **Appearance and Content:** Other than as required in this paragraph, no electronic document may be intentionally manipulated to change how the source document would have appeared, without prior agreement of the Receiving Party, except that hidden information (such as redline or comments) will be revealed. Additionally, all emails will be produced with the BCC field visible, to the extent it is available with the document. "Dynamic fields" (such as auto-date and time) shall be produced showing the field code (*e.g.*, [AUTODATE]), rather than the values for such fields existing at the time the file is processed. Therefore, subject to any appropriate redaction and any revealed hidden information, each document's electronic image shall convey

the same information and image as the original document. This means that font size, bold, italics, underline and other font features shall be maintained. If a document is illegible or unviewable to the Receiving Party, the Parties shall discuss appropriate measures to address the issue through an agreed-upon resolution, such as, for example, enlarging font size.

7. **Document Numbering for TIFF Images:** Each page of a produced document, produced in TIFF file format shall have a legible, unique Bates number electronically “burned” onto the image at a location that does not obliterate, conceal or interfere with any information from the source document. The Bates number for each document shall be created so as to identify the Producing Party. Each page of each production shall have a unique number. Each page of each production shall have a unique number of up to eight digits. The unused digits of the unique number shall be filled with placeholder zeros (0) to facilitate electronic sorting of the documents. Any Producing Party producing ESI in Native Format, as set forth above, shall produce a slipsheet in Black and White Group IV* TIFF that is endorsed with the Bates number. If a document is produced subject to a claim that it is protected from disclosure under the Protective Order, the appropriate confidentiality designation, as provided under the Protective Order, shall be burned electronically on each page of such document. Any redacted page shall also include the word “Redacted” burned on the TIFF image at the location of the redaction(s).

8. **Searchable Text:** To the extent technologically possible, all Responsive ESI shall be produced with corresponding searchable text in a separate text file on a per image or per document basis.

9. **Production Media:** The Producing Party shall produce documents on readily accessible, computer or electronic media as the Parties may hereafter agree upon, including CD-ROM, DVD and external hard drive (with standard PC compatible interface or access to a secure

On-Line Repository agreed upon by the Parties) or via secure FTP site. Each piece of Production Media shall be assigned a production number or other unique identifying label corresponding to the date of the production of documents on the Production Media as well as the sequence of the material in that production.

10. **Original Documents**: The Producing Party shall retain native electronic source documents for all ESI produced in This Litigation. The Producing Party shall take all reasonable measures to maintain the original native electronic source documents in a manner so as to preserve the metadata associated with these electronic materials as it existed at the time of production in the event review of such metadata becomes necessary.

11. **Confidentiality of Produced ESI**: Nothing in this Order is intended to be inconsistent with the Protective Order that the Court will enter in This Litigation, and where anything in this Order is inconsistent with the terms of the Protective Order, the terms of the Protective Order shall prevail. If a document is produced subject to a claim that it is protected from disclosure under the Protective Order, the appropriate confidentiality designation, as provided under the Protective Order, shall be burned electronically on each page of such document.

12. **Third-Party Software**: To the extent ESI produced pursuant to this Order cannot be rendered or viewed without the use of proprietary third-party software, the Parties shall cooperate and seek to attempt to minimize any expense or burden associated with the production of such ESI. The Parties shall meet and confer to address such issues as may arise with respect to obtaining access to any such software and operating manuals which are the property of a third-party.

E. PRIVILEGE LOGS

1. **Scope of Privilege Log**: The Producing Party will log all documents over which the Party claims attorney-client, attorney work product, common interest, joint defense privilege,

or any other applicable privilege or immunity designation on a privileged document log in accordance with Federal Rule of Civil Procedure 26(b)(5) except as allowed herein. The Parties will not need to log materials subject to attorney-client privilege, work product, and/or other immunity from discovery that were created on or after the filing of the Complaint. The Parties further agree that they will not need to log any communications between the parties and their trial counsel. The Parties will defer production of privilege logs until their first productions are substantially complete, but in no event shall be later than two (2) weeks prior to the fact discovery cutoff.

2. **Inadvertent Disclosure of Confidential Information:** The Parties agree that any inadvertent failure to designate information with one of the designations described in the Protective Order (including any amendments to that Order) shall not be deemed a waiver of, nor prejudice to, any applicable designation with respect to the confidentiality of such information or document(s), provided that the Producing Party notifies the Receiving Party in writing promptly after discovery of such inadvertent failure to designate. A Receiving Party shall not be in breach of the Protective Order for any use of such discovery information before the Receiving Party received notice of the inadvertent failure to designate. Once a Receiving Party has received notice of the inadvertent failure to designate pursuant to this provision, the receiving party shall treat such discovery information as the appropriately designated level pursuant to the terms of the Protective Order. If discovery material is designated after production, the Receiving Party shall within five (5) business days collect any copies that have been provided to individuals so they can be relabeled with the correct confidentiality designation.

3. **Inadvertent Disclosure of Privileged Information:** The Parties agree that any inadvertent production of material over which the Producing Party claims attorney-client, attorney

work product, common interest, joint defense privilege, or any other applicable privilege or immunity designation, shall not be deemed a waiver of that claim of privilege, provided that the Producing Party notifies the Receiving Party in writing promptly after determining that privileged information has been produced. A Receiving Party shall not be in breach of the Protective Order for any use of such discovery information before the Receiving Party receives notice of the Producing Party's privilege claim. Once a Receiving Party has received notice of the inadvertent production, the Receiving Party shall within five (5) business days comply with Federal Rule of Civil Procedure 26(b)(5)(B). Any notification by the Producing Party pursuant to this Paragraph shall be accompanied by a privileged document log separately identifying each document over which the Producing Party claims privilege.

4. **Challenges to Claims of Privilege:** Nothing in this Stipulation shall prevent the Receiving Party from challenging the propriety of the attorney-client, attorney work product, common interest, joint defense privilege, or any other applicable privilege or immunity designation (based on information independent of the content of the asserted privileged materials).

F. REDACTIONS RELATING TO ATTORNEY-CLIENT, ATTORNEY WORK PRODUCT, COMMON INTEREST, JOINT DEFENSE, OR ANY OTHER APPLICABLE PRIVILEGE OR IMMUNITY, AND CHALLENGES THERETO

1. **Scope of Redactions:** Parties shall redact only those portions of a document that fall within the scope of the attorney-client, attorney work product, common interest, joint defense privilege, or any other applicable privilege or immunity, and not the entire document or page unless the entire document or page is within such scope.

2. **Logging of Redacted Documents:** When a document is redacted on the basis of privilege, the party claiming privilege shall list the information pertaining to the redacted portion of the document on a privilege log as set forth above.

3. **Challenging Document Redactions:** A Receiving Party may challenge a redaction of privilege at any time after the document or a privilege log identifying the document subject to such redaction is produced. A Receiving Party does not waive its right to challenge a redaction by electing not to challenge promptly after the subject document or privilege log identifying it has been produced. A Receiving Party may challenge a Producing Party's redaction of privilege from production by notifying the Producing Party, in writing, of its good faith belief that the redaction or designation was not proper, including a brief explanation of the basis of the dispute with regard to each redaction at issue. Thereafter, the Producing Party shall have five business (5) days to review the redacted or designated material, to consider the circumstances, and to meet and confer with the Receiving Party. If no resolution can be reached after those five business (5) days, the Receiving Party may submit the issue as a discovery dispute in accordance with the rules of the Court.

G. EXPERT DISCOVERY

1. **Application of Federal Rules to Expert Discovery:** The Parties agree that expert discovery shall be governed by the Federal Rule of Civil Procedure 26.

2. **Non-Discoverability of Expert Report Drafts:** The Parties agree that drafts of expert reports are not discoverable.

3. **Expert Permanent and Support Personnel:** The Parties agree that an approved expert's permanent and support personnel, including assistants, translators, graphics personnel, trial consultants, and the like, are included within the non-discoverability provisions of Federal Rule of Civil Procedure 26.

H. DEPOSITIONS

1. **Duration:** The Parties agree that depositions will be limited to seven (7.0) hours of testimony per day. The Parties agree that personal depositions will be limited to one day unless

otherwise agreed. For personal depositions of witnesses for which a translator is required, the Parties agree that depositions will be limited to ten (10.0) hours of testimony. However, to avoid undue burden on translated witnesses, no witness shall be required to sit for more than seven (7.0) hours of time on the record in a single day unless by agreement of the interested parties involved. The Parties will meet and confer concerning the duration of corporate depositions, as well as depositions of witnesses that are both in one's personal capacity and as a corporate representative. The Parties agree that if a witness will be deposed in his or her personal capacity and on behalf of a party, absent further negotiation on a case-by-case basis, the Parties will strive to ensure both depositions will be conducted during the same time period.

2. **Location:** For a witness located within the United States, the Parties agree to conduct the deposition at a location convenient to the witness or witness's counsel as reasonably determined by the Producing Party. For a witness located outside of the United States, except as otherwise agreed, the Parties agree to conduct the deposition virtually or at a location reasonable agreeable to the witness, at the election of the Producing Party. The Parties agree to coordinate depositions to the extent possible with the goal that all depositions to be taken in any foreign country may be taken during the same trip. The Parties agree that all depositions, whether taken within or outside of the United States, shall be governed by the Federal Rules of Civil Procedure and any agreement between the Parties.

3. **Virtual Depositions:** The Parties recognize that depositions may need to be conducted remotely in this litigation. If depositions will be held virtually, the parties will meet and confer concerning a protocol for the conduct of such depositions.

4. **Number of Witnesses:** The Parties agree to meet and confer concerning the number of Rule 30(b)(1) and Rule 30(b)(6) fact depositions (party and third-party) per side.

I. MISCELLANEOUS

1. **English Language:** To the extent any ESI exists in more than one language, the ESI shall be produced in English, if available.

2. **Duplicate Production Not Required:** A Party producing ESI in electronic form need not produce the same document in paper format.

3. **Cooperation.** The Parties shall, as necessary, meet and confer to exchange information regarding issues associated with any production of ESI, including, but not limited to, database field definitions and structure or document delivery mechanisms.

4. **Variance.** Any practice or procedure set forth herein may be varied by written agreement of the Parties.

5. **Paper Discovery:** Nothing in this Order is intended to interfere with, preclude, alter, or otherwise affect the Parties' independent obligations to engage in discovery involving and, where appropriate, produce materials that exist only in paper format. All paper documents shall be produced as static images. The images will be black-and-white, single page, 300 DPI, Group IV* TIFF images with corresponding OCR text in document level .txt format and standard load files, which can be used with commercially available litigation software packages. Producing paper documents in such form does not change their character from paper documents into ESI. All other metadata that does not exist as part of the original document need not be produced for paper documents produced as TIFF images. The parties shall meet and confer with respect to the unitizing of hard copy documents and grouping of documents into families.

6. **Paper Discovery and COVID-19:** To the extent the retrieval of paper documents creates an unreasonable burden or undue costs on the Producing Party because of the ongoing COVID-19 pandemic, the Producing Party agrees to notify the other parties and explain the undue circumstances. If after considering the Producing Party's explanation the requesting party insists

that paper documents be produced, the burden shifts to the requesting party to demonstrate a particular need for such evidence that justifies the burden of retrieval, and further subject to the Producing Party's claim of undue burden or cost. The Parties agree that they will meet and confer should a dispute arise regarding paper document production, and if the Parties cannot reach an agreement, the Parties may submit the issue as a discovery dispute in accordance with the rules of the Court.

7. **Replacement Images**: In the event that an already produced document or set of documents has to be re-produced or a new Production Load File or "overlay" is produced for any production, the new production shall always maintain the same Bates number for any re-produced documents, with the addition of a suffix at the end of the Bates number, and without creating a new database record.

8. **Metadata as Evidence**: This Order shall not be construed to affect whether information contained in the metadata produced shall be admissible evidence about the corresponding document; rather, the Parties' positions with regard to admissibility shall be preserved for trial.

STIPULATED TO AND APPROVED BY:

Dated: December 23, 2020

/s/ Eric Hochstadt

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ORDER

Based on the foregoing stipulation, and good cause appearing therefore, **IT IS SO ORDERED** this _____ day of _____, 202_.

The Honorable Alison J. Nathan